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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 27777 | 7590 | 06/05/2009 | EXAMINER | |
| PHILIP S. JOHNSON | | | HOPKINS, CHRISTINE D | |
| JOHNSON & JOHNSON | | | | |
| ONE JOHNSON & JOHNSON PLAZA | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/598,593 | REVIE ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTINE D. HOPKINS | 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 50-88 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 50-74, 76-79, 81-84 and 86-88 is/are rejected.
- 7) Claim(s) 75, 80 and 85 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/5/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 67, it is unclear what constitutes a "sharper profile" with reference to the cross section of the threaded portion.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 50-67, 86 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (U.S. Patent No. 6,499,488). Hunter et al. (hereinafter Hunter) teaches an implantable marker/sensor. Regarding claims 50, 53, 58-62, 65-67, Hunter teaches a implantable marker comprising: a housing **26** having an inner cavity **29**, the housing having an outer surface, the outer surface providing a bone anchor **14** having a threaded formation and a barb at its tapered tip which engages with bone when implanted in use to retain the marker in the bone; and a marker **28** secured within the cavity, wherein the marker is detectable by a tracking system (Figs. 1A and 1B and col. 4, lines 8-15). Regarding claim 51, the marker and cavity are configured such that at least a part of the marker is capable of being positioned within the bone in use (col. 3, lines 63-67 - col. 4, lines 1-3 and col. 6, lines 11-20). Regarding claims 52 and 55, the marker **28** is hermetically sealed (col. 6, lines 1-10). Regarding claim 54, the threaded formation of anchor **14** encourages "bone on growth" (Figs. 1A and 1B).

Regarding claims 56 and 57, the marker is wirelessly detectable using electromagnetic radiation (col. 4, lines 23-35 and col. 5, lines 16-22). Further regarding claim 60, the housing and bone anchor may be integrally formed (col. 5, lines 55-58). Regarding claims 63 and 64, the housing has a connector **31** for releasably engaging with an insertion tool and preventing relative rotation between the marker and insertion tool when connected (col. 6, lines 26-32).

Regarding claim 86, Hunter teaches an implantable marker comprising: a housing **(26, 14)** having a body section, a distal end and a proximal end, wherein the body section is cylindrical and defines a cavity therein, the distal end is tapered, the proximal end has a connector **31** for engaging an insertion tool, and wherein the housing has an outer surface **18** bearing a screw thread; and a marker **28** enclosed within the cavity, the marker being hermetically sealed and wirelessly detectable by a tracking system (col. 4, lines 8-15) using electromagnetic radiation (col. 5, lines 16-22), and wherein the implantable marker is retained in the bone in use by the interaction of the screw thread **18** and surrounding bone and wherein the marker **28** is located within the bone when the implantable marker is implanted in the bone (Figs. 1A and 1B). Regarding claim 87, the implantable marker may further comprise additional sensors for detecting a property in the region around the marker (col. 6, lines 1-10).

6. Claims 69-73, 76-79 and 81-84 rejected under 35 U.S.C. 102(e) as being anticipated by Mazzocchi et al. (U.S. Pub. No. 2004/0030236). Mazzocchi et al. (hereinafter Mazzocchi) teaches an assembly for internally engaging a patient's skull. Regarding claims 69 and 70, Mazzocchi discloses a kit comprising: a guide instrument **700** having a guide channel **702** for receiving an implantable marker; an insertion tool **(606, 1320)** having an elongate body and a channel (Figs. 11 and 13), receivable within the guide channel and translatable along the guide, the insertion tool having a distal end for releasably engaging an implantable marker **100**; the implantable marker **100** comprising a housing defining a cavity and a marker **300** detectable by a tracking system, wherein the insertion tool is operable to drive the implantable marker **100** into

the bone ([0040], Figs. 3 and 11). Regarding claim 71, the insertion tool (**606, 1320**) has an aperture for receiving the thread therethrough (Fig. 13). Regarding claims 72 and 77, the implantable marker **100** has a distal end bearing a bone (and skin) penetrating tip **112** [0038]. Regarding claims 73 and 78, a self-drilling base **100** is located on the distal tip of the guide instrument. The self-drilling base has a plurality of bone penetrating teeth and at least a first and second plurality of bone penetrating teeth on opposing sides ([0049] and Fig. 10).

Regarding claim 76 and 79, the kit further comprises a drill **1000** receivable within the guide channel and translatable along the guide channel, the drill having a drill bit (tapered tip) at a distal end for creating a hole in bone (Fig. 10).

Regarding claims 81-84, Mazzocchi teaches a method for implanting an implantable marker in a bone, wherein the marker is detectable by a tracking system, the method comprising: puncturing the skin with a power-driven insertion tool and positioning a distal end of the instrument adjacent the bone; drilling a hole in the bone; driving the implantable marker **100** into the bone from the instrument; and withdrawing the instrument while leaving the marker implanted in the bone [0038].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (U.S. Patent No. 6,499,488). Hunter discloses the invention as claimed, see rejection supra; however Hunter does not disclose expressly that the cross section of the thread is in the shape of a rounded trapezium. Instead, Hunter indicates that the marker has a threaded portion configured to be secured into bony structures (col. 3, lines 63-67 - col. 4, lines 1-3). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a thread having a cross section in the shape of a rounded trapezium because Applicant has not disclosed that such a shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Hunter's threaded portion and applicant's invention, to perform equally well with either the shape taught by Hunter or the claimed "rounded trapezium" because both would perform the same function of securing the marker within bone. Therefore, at the time of the invention it would have been *prima facie* obvious to modify Hunter to obtain the invention as specified in claim 68 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Hunter.

9. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzocchi et al. (U.S. Pub. No. 2004/0030236) in view of Hunter et al. (U.S. Patent No. 6,499,488). Mazzocchi discloses the invention as claimed, see rejection supra; however Mazzocchi fails to disclose including a magazine for storing the implantable markers. Hunter discloses an implantable device for sensing location and positioning.

Regarding claim 74, Hunter teaches that the body enclosing the sensor may include a cartridge for removably securing a sensor in the body. At the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated a cartridge for holding sensors as taught by Hunter, into the body of an instrument for implanting markers as taught by Mazzocchi, as it is desireable to use a multiplicity of any type of markers or sensors to improve accuracy of detection.

10. Claim 88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (U.S. Patent No. 6,499,488) in view of Govari et al. (U.S. Pub. No. 2003/0023161). Hunter discloses the invention as claimed, see rejection supra; however Hunter does not disclose expressly that the sensor is sensitive to one of pressure, temperature, biological or chemical activity. Govari et al. (hereinafter Govari) teaches an implantable device for determining and producing position and orientation coordinates. Regarding claim 88, Govari teaches sensors for determining temperature and pressure, as well as other properties, in addition to the sensors for determining coordinates of the implantable device [0057]. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have constructed additional sensors in an implantable device as taught by Hunter, of means for measuring physiological parameters as suggested by Govari, in order to determine the state of the tissue with which the implant contacts.

Allowable Subject Matter

11. Claims 75, 80 and 85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claim 75, the prior art of record does not teach or fairly suggest a kit for implanting an implantable marker in bone as claimed by Applicant, wherein the magazine of the guide instrument includes a dispensing mechanism configured to automatically insert a further implantable marker into the guide channel after a current implantable marker has been implanted.

Regarding claim 80, the prior art of record does not teach or fairly suggest a kit for implanting an implantable marker in bone as claimed by Applicant, wherein the insertion tool includes the drill and wherein the distal end of the insertion tool is a separable part of the insertion tool into which at least the drill bit can be releasably fastened to provide the insertion tool. Regarding claim 85, the prior art of record does not teach or fairly suggest a method for percutaneously implanting an implantable marker in a bone, wherein the instrument includes a guide channel extending at least partially along a longitudinal axis of the instrument, and the step of drilling the hole includes translating a drill at least partially along the guide channel of the instrument. The prior art teaches a guide instrument which is solid for self-drilling, and therefore a drill is not translated along the guide channel of the instrument.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

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